UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

GUARDANT HEALTH, INC.,
a Delaware corporation,

Plaintiff,

vs.

NATERA, INC.,
a Delaware corporation,

Defendant.

Case No. 4:21-cv-04062-EMC

[PROPOSED] ORDER GRANTING PLAINTIFF GUARDANT HEALTH, INC.'S MOTION FOR TEMPORARY RESTRAINING ORDER

Date: June 3, 2021
Time: 1:45 p.m. (Pacific Time)
Courtroom: Zoom Webinar

Complaint Filed: May 27, 2021

Now before the Court is Plaintiff Guardant Health, Inc.'s Motion for a temporary restraining order. Having considered the Plaintiff's Motion, the record in this matter, and the arguments of counsel, the Court **GRANTS** Guardant's Motion.

Plaintiff and Defendant compete in the field of cancer assays. Specifically, Plaintiff recently launched its "Reveal" product, a plasma-only test for detecting minimal residual disease (MRD) in patients with colorectal cancer (CRC) based on fragments of circulating tumor DNA (ctDNA) in the bloodstream. Defendant offers a competing assay, Signatera, which is also used to test for MRD in CRC patients, but depends on tumor tissue to identify a panel of mutations to track in blood for that patient. Coinciding with Reveal's launch, Defendant began comparing Signatera to Reveal in a series of promotions and advertisements to the parties' mutual customers and potential customers, including oncologists and other health care professionals, as well as research and treatment facilities working with cancer patients.

These advertisements, including an "Evidence Review," a "white paper," and a "Performance Comparison," claim to show that Signatera is superior to Reveal on a number of

metrics. These claims of superiority are based on comparing data from two studies, Parikh et al., which only examined Reveal, and Reinert et al., which only examined Signatera. However, as the evidence presented by Plaintiff demonstrates, the two studies are dissimilar, and Defendant's reliance on them to draw unfavorable comparisons with Plaintiff's assay is unsupported, unfair, and deceptive.

The evidence further shows that the Parties will be presenting information regarding their competing assays at the largest professional oncology meeting in the United States, the annual ASCO Conference, which is due to begin on June 4, 2021. Plaintiff thus argues—and the Court agrees—that immediate injunctive relief is necessary to avoid irreparable harm to Plaintiff, its reputation, and its goodwill with customers.

"The standard for issuing a TRO is identical to the standard for a preliminary injunction." *Cisco Sys., Inc. v. Shenshen Usource Tech., Co.*, No. 5:20-cv-4773, 2020 WL 5199434, at *6 (N.D. Cal. Aug. 17, 2020) (granting motion for temporary restraining order enjoining defendants from violating Lanham Act, and incorporating two similar orders as exhibits) (citing *Stuhlbarg Int'l Sales Co., Inc. v. John D. Brush & Co.*, 240 F.3d 832, 839 n.7 (9th Cir. 2001); *Lockheed Missile & Space Co. v. Hughes Aircraft,* 887 F. Supp. 1320, 1323 (N.D. Cal. 1995)). "A plaintiff seeking preliminary injunctive relief must establish that":

(1) it is likely to succeed on the merits;

(2) it is likely to suffer irreparable harm in the absence of preliminary relief;

(3) the balance of equities tips in his favor; and

(4) an injunction is in the public interest.

Id. (quotations omitted, formatting added) (quoting *Winter v. Natural Res. Defense Council, Inc.*, 555 U.S. 7, 20 (2008)).

Here, the Court finds that Plaintiff has met this standard of showing an entitlement to temporary injunctive relief. Defendant's misleading use of cross-study data to compare the parties' competing CRC detection assays is inherently deceptive, and Plaintiff is likely to succeed on the merits of its false advertising claims under § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a). *See Southland Sod Farms v. Stover Seed Co.,* 108 F.3d 1134, 1139 (9th Cir. 1997);

see also Clorox Co. v. Reckitt Benckiser Grp. PLC, 398 F. Supp. 3d 623, 635 (N.D. Cal. 2019)..

As Plaintiff's witnesses have testified, and courts have held, it is inherently improper and unfair to directly compare two products based on disparate studies that did not evaluate the two products head-to-head:

> it is a fundamental principle of clinical testing that one cannot infer efficacy comparisons between two products when, as here, those products have not been tested against one another in a well-controlled head-to-head clinical study.

Zeneca Inc. v. Eli Lilly and Co., No. 99-cv-1452, 1999 WL 509471, at *35 (S.D.N.Y. Jul. 19, 1999) (emphasis added) (granting preliminary injunction, concluding: "Unless and until the STAR trial has been completed and proves that hypothesis, it is a clear violation of the Lanham Act for Eli Lilly to continue making this comparative establishment claim.")

It is undisputed that Defendant has failed to cite any studies directly comparing Signatera and Reveal. Because Defendant's use of data drawn from disparate studies that not evaluate the two products together, and because Defendant's comparisons are false and misleading, Plaintiff has met its burden of showing a likelihood of success on the merits of showing that Defendant's advertising violates § 43(a) of the Lanham Act. *Southland Sod*, 108 F.3d at 1139 (claims of product superiority based on testing are false if the "tests 'are not sufficiently reliable to permit one to conclude with reasonable certainty that they established' the claim made.")

Because Plaintiff has made this showing of a likelihood of success on the merits, irreparable harm may be presumed. 15 U.S.C. § 1116(a). Moreover, Plaintiff has demonstrated a significant risk of irreparable harm, including loss of customers and the loss of goodwill, should Defendant be unrestrained from continuing its advertising campaign, particularly given the imminent ASCO Conference. In addition, the Court finds that both the equities and the public interest weigh in favor of granting temporary injunctive relief.

Accordingly, Defendant, its officers, agents, servants, employees and attorneys, and all persons in active concert or participation with Defendant, are hereby immediately enjoined and restrained from making any statements to Defendant's or Plaintiff's customers or potential customers, including oncologists and other physicians, cancer researchers, health care institutions, biopharmaceutical companies, and genetic laboratories, whether orally, in writing, or

through any electronic means, including emails, PowerPoint presentations, or distributing copies of the above-referenced "Evidence Review," "white paper," and "Performance Comparison," that compare Signatera to Reveal, or claim that Signatera is superior than Reveal, or that describe Reveal as being untested, inaccurate, or insensitive, based on data drawn from any studies that do not directly compare the two assays. This specifically includes any statement or inference that:

1. Signatera has a lower "failure rate" than Reveal;
2. Signatera has superior "pre-surgical sensitivity" than Reveal;
3. Signatera has a superior 30-day post-surgical negative and/or positive predictive value than Reveal, or that data for Reveal is "not reported" or "not validated";
4. Signatera provides a superior "diagnostic lead time" than Reveal;
5. Signatera provides a superior longitudinal negative predictive value than Reveal;
6. Signatera provides superior hazard ratios than Reveal; or that
7. Signatera has superior serial or longitudinal sensitivity than Reveal.

This Temporary Restraining Order shall take effect immediately and shall remain in effect until a Hearing on Plaintiff's Motion for a Preliminary Injunction.

This Court "'is afforded wide discretion in setting the amount of the bond," and "'the bond amount may be zero if there is no evidence the party will suffer damages from the injunction.'" *Cisco Sys*, 2020 WL 5199434, at *13 (quoting *Connecticut Gen. Life Ins. Co. v. New Images of Beverly Hills,* 321 F.3d 878, 882 (9th Cir. 2003)). Here, the Court concludes that a bond in the amount of $0 is appropriate.

ORDER TO SHOW CAUSE: The Court hereby fixes the Hearing for Plaintiff's Motion for a Preliminary Injunction, which shall be scheduled pursuant to FED. R. CIV. P. 65(b), for June 3 2021 at 1:45 p.m.

The Court further fixes June 2, 2021, as the time within which this Order and all supporting pleadings and papers must be served upon Defendant.

IT IS SO ORDERED.

Dated: _____, 2021 at _____ a.m./p.m.

Hon. Edward M. Chen
United States District Judge